

**REMARKS****A. Summary of the Office Action**

Claims 43-48 were pending in the application. In the Office Action dated April 7, 2004, claims 43-47 were rejected under 35 U.S.C. § 103(a). Claim 48 was objected to as being dependent upon a rejected independent base claim, namely claim 47. Claims 47 and 48 remain pending.

**B. Status of the Application**

In response to the Office Action, claims 43-46 have been cancelled to expedite prosecution. Claim 47 has been amended to clarify aspects of the invention. Claim 48 has been amended to be in independent format incorporating the features of original claim 47.

**C. Response to Claim Rejections**

In the Office Action, the Examiner rejected claim 47 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,558,838 (Uffenheimer), and further in view of U.S. Patent No. 5,171,538 (Tremmel et al.), or in the alternative, U.S. Patent No. 6,149,872 (Mack et al.). The Examiner asserts that Uffenheimer teaches all of the claimed features except a reagent cartridge containing a lyophilized reagent. Examiner further asserts that Tremmel et al. discloses a reagent supply system with a reagent space provided on the instrument and reagent vessels received in the reagent space. The Examiner further asserts that Mack et al. discloses a modular reagent cartridge that includes a plurality of reagent containers directly interconnected by integrally formed coupling devices. The Examiner concludes it would have been obvious to one of ordinary skill in the art at the time of the invention to recognize that a cartridge may also be used to supply a reagent to the system of Uffenheimer.

Claim 47 is directed to an automated analytical system for sequential-injection sample analysis. The system as claimed includes a multipositional stream-selection device, a fluid propulsion device, a source of sample in fluid communication with the multipositional stream-selection device, and a reservoir containing a lyophilized reagent which is to be dissolved or a solution of reagent which is to be diluted. The reagent, when dissolved in or diluted by a solvent, forms a reconstituted agent capable of

reacting with a component of the sample to form a reaction product detectable by an automated analytical system. The automated analytical system of claim 47 further includes "(e) a source of solvent, in fluid communication with the multipositional stream-selection device, for dissolving or diluting the lyophilized or concentrated reagent." Claim 47 further recites "(f) a detector in fluid communication with the multipositional stream-selection device," and "(g) a central processing unit, operatively connected to the multipositional stream-selection device, and constructed and arranged for automatic control of fluid flow between the multipositional stream-selection device, the sample source, the reservoir containing the lyophilized or concentrated reagent, the solvent source, and the detector."

Uffenheimer teaches a sample preparation apparatus for preparation of a blood sample which dispenses measured amounts of a blood sample and a dilutant into a reaction tube which contains a predisposed reagent. Uffenheimer does not disclose, teach or suggest an automated analytical system for sequential-injunction sample analysis as set forth in amended claim 47. Uffenheimer is silent with respect to an automated analytical system that includes "a reagent reservoir containing a lyophilized reagent which is to be dissolved or a solution of reagent which is to be diluted, wherein the reagent, when dissolved in or diluted by a solvent, forms a reconstituted reagent that is capable of reacting with a component of the sample to form a reaction product detectable by the automated analytical system" (emphasis added).

Uffenheimer also does not teach or suggest an automated analytical system as claimed that includes "a source of solvent, in fluid communication with the multipositional stream-selection device for dissolving or diluting the lyophilized or concentrated reagent." Uffenheimer further is silent with respect to an automated analytical system as claimed that includes "a central processing unit, operatively connected to the multipositional stream-selection device, and constructed and arranged for automatic control of fluid flow between the multipositional stream-selection device, the sample source, the reservoir containing the lyophilized or concentrated reagent, the solvent source, and the detector." Uffenheimer is simply silent with respect to these claimed elements and provides no teaching or suggestion of a system with these elements.

The Examiner asserts that claim 47 would be obvious to one of ordinary skill in the art by combining Uffenheimer with the teachings of Tremmel et al. or Mack et al. Tremmel et al., however, discloses a reagent supply system for a medical analytical instrument. Modifying the teachings of Uffenheimer in view of Tremmel et al.'s reagent supply system still not result in the automated analytical system of claim 47. The reagent supply system of Tremmel et al. would combine with Uffenheimer's reagent tube 32 that includes the predisposed reagent (see Figure 2A, Column 1, lines 5-8, and Column 3, lines 24-26). Alternatively, Tremmel et al.'s reagent supply system would be combined with Uffenheimer pump 108 and the supply of reagent 110 aspirated in a measured quantity into the pump into the reaction tube 34 (see Figure 8 and Column 5, lines 41-54). Modifying the blood sample preparation apparatus of Uffenheimer to provide Tremmel et al.'s reagent supply system that provides reagent into the reagent tube would still not result in the claimed automated analytical system. The combination would still not include the reservoir containing a lyophilized or concentrated reagent that when dissolved or diluted by a solvent forms a reconstituted reagent, the source of solvent for dissolving or diluting the reagent, and a central processing unit operatively connected to a multipositional stream-selection device and constructed and arranged for automatic control of fluid flow between the multipositional stream-selection device, the sample source, the reservoir containing the lyophilized or concentrated reagent, the solvent source, and the detector. Therefore, the combination of Uffenheimer and Tremmel et al. does not teach or suggest the claimed invention set forth in amended claim 47. Any modification to the teaching of the references to provide the claimed automated analytical systems would only be apparent to one of ordinary skill in the art after fully understanding the present invention and applying impermissible hindsight analysis such that claim 47 is patentable over the combination of references.

Regarding Uffenheimer in combination with Mack et al., this secondary reference is directed to a modular reagent cartridge for "the supply of ready-to-use, biochemical reagents in liquid form, whose purpose is to enable a simple loading into and use in a fully automated analyzer" (column 1, lines 1-6). Modifying the teachings of Uffenheimer in view of Mack et al. would result in modifying the reagent portion of the Uffenheimer system, including the reagent tube 32 or the reagent source 110 in combination with the

reagent pump 108 that provides the reagent into the reagent tube 32 (Figure 8, and Column 5, lines 41-54).

Mack et al. does not correct the deficiencies of Uffenheimer. Uffenheimer and Mack et al. alone or in combination, do not teach or suggest an automated analytical system for sequential injection sample analysis that has a reservoir containing a lyophilized reagent which is to be dissolved or a solution of reagent which is to be diluted, wherein the reagent, when dissolved or diluted by a solvent, forms a reconstituted reagent capable of reacting with a component of the sample to form a reaction product detectable by an automated analytical system as claimed. Further, the combination of references does not teach or suggest an automated analytical system with a source of solvent for dissolving or diluting the reagent, or the central processing unit operatively connected to the multipositional stream-selection device and constructed and arranged for automatic control of fluid flow between the multipositional stream-selection device, the sample source, the reservoir containing the reagent, the solvent source, and the detector. Any modification of the teachings of Uffenheimer in combination with Mack et al. would only be apparent to one of ordinary skill in the art after fully understanding the present invention and applying impermissible hindsight analysis. Therefore, applicants respectfully submit that claim 47 as amended is patentable over the applied references and is in condition for allowance. Applicants further submit that the amendments to claim 47 are fully supported by the application as originally filed, do not add new matter, and do not modify the claim so as to necessitate a new search.

Claim 48 was objected to by the Examiner as being dependent upon a rejected base claim. Claim 48 has been amended to be in independent format and to incorporate the features of original claim 47. Therefore, applicants respectfully submit that claim 48 is patentable and is in condition for allowance.

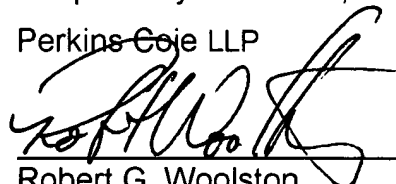
#### D. Conclusion

In view of the foregoing, applicants respectfully submit the pending claims are patentable over the cited references and are in condition for allowance. A Notice of Allowance is, therefore, respectfully requested. If the Examiner has any questions or

believes a telephone conference would expedite prosecution of this application, the Examiner is encouraged to call the undersigned at (206) 359-3259.

Respectfully submitted,

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